

Fourteenth International Workshop on Physical Characterization of Pharmaceutical Solids

IWPCPS® - 14

Universitat Politècnica de Catalunya
Barcelona, Spain **June 25 - 28, 2012**



Preliminary Program

■ **Integrated API and DP Design**

Chaired by Dr. S. Luthra, Pfizer, USA

API and DP R&D activities are intimately linked. An interface between API and DP development groups is needed to strike a balance between API attributes such as optimum solid form and particle properties such as particle size and surface area, etc. and DP design space to ensure consistent bioperformance and stability. In this session industrial and academic subject matter experts will present experimental and theoretical examples of integrated API and DP design across multiple DP platforms such as solid oral, liquids, transdermals, etc.

■ **Particle Engineering and Phase Transformations**

Chaired by Dr. T. Carvajal, Purdue University, USA

Particle/Crystal engineering is gaining interest and it involves the design of crystals or particles with desired properties for specific functionality. Particle engineering is a fast emerging, cross-disciplinary field that involves various approaches such as designed crystallization, co-crystals, spray drying, supercritical fluids, micromolding, microfluidics, etc. All require an improved understanding of the resulting material structure that is relevant to pharmaceuticals, mainly active ingredients, with the aid of high resolution analytical tools. This promising field is, in the pharmaceutical business, in part as a response of the material to physical changes, such as phase transformations, crystal dislocations and surface interactions when subjected to processing and/or exposed them to temperature and relative humidity. The nature of these changes may induce various drug-drug, drug-excipient and drug-water interactions hence different performance and stability properties of the solids. This session will discuss recent and significant advances on the crystal/particle engineering field with relevant discussion on the production, analysis, stability and performance with emphasis on phase transformations, surface modifications and interactions.

■ **Emerging and Advancing Solid State Technology and Theory**

Chaired by Dr. P. Luner, Boehringer-Ingelheim, USA

This session will focus on solid-state characterization technologies and theoretical developments that are currently emerging from the "laboratory" to mainstream application in the industry. As developmentally complex API forms and formulation/processing methods are required for drug enablement, more sensitive, robust and precise methods will be needed to characterize API behavior and interactions in dosage forms. Molecular complexity of APIs for newer targets also requires advancement of our theoretical understanding of molecular crystals to keep pace with methods that can distinguish solid forms with increasing sensitivity. Presentations in this session will highlight: current developments in hybrid techniques, increased quantitative sensitivity of new and established techniques, and application of structural informatic, molecular dynamic, surface and thermodynamic approaches. In addition, the session will emphasize novel methods that can be used to interrogate critical aspects of solid-state behavior relevant to API physical and chemical stability.

■ **Foreign Matter**

Chaired by G. Nichols, Pfizer, UK and Dr. I. Saracovan, assa Inc. USA

New generations of formulations and drug products developed and marketed in recent years by the pharmaceutical industry demand an unprecedented level of precise control of particle size to micron and submicron levels. The need for such precise control of particle size not only pushes the boundaries of available manufacturing technologies but it also raises the challenge for a tight control of foreign particles that may unwillingly be present in the drug product. A successful control of foreign particles is highly dependent on the capabilities and limitations of both the instrumentation and the methods used for the detection and analysis of contaminants. This is the main reason why the detection and analysis of foreign particles in drug products remains an area of sustained scientific and technological effort of both analytical instrumentation and pharmaceutical industries. The "Foreign Matter" session is dedicated to present new developments on the detection and analysis of foreign particles area as well as real- and case-studies and strategies or approaches for the control of solid contaminants in formulations and drug products.

■ **Theoretical and Empirical Methods for Resolving Relative Stabilities of Polymorphs**

Chaired by Dr. I. Rietveld, University of Paris, France

This session discusses the theoretical stability of polymorphs. In pharmaceutical industry it is highly important to know as much as possible about different forms of a compound and their stabilities. Nowadays polymorphs of a certain compound and their stability can be calculated completely based on theoretical methods. Presentations of methods that aim at obtaining relative stabilities of polymorphs are welcome.

■ **Dissolution Testing for the 21st Century**

Chaired by Dr. T. Rades, University of Otago, New Zealand

This session would include topics such as: Use and importance of biorelevant media, MIVC, solid state characterization during dissolution, imaging of dissolution, miniaturization, modeling, and dissolution testing of fast dissolving materials.

■ **Precipitation of Solids in the GI Tract**

Chaired by Dr. B. Abrahamsson, AstraZeneca, Sweden and Dr. J. Rantanen, University of Copenhagen, Denmark

The key topic here is "enabling formulations". It includes the topics nucleation, crystal growth and precipitation.

■ **Defining an Effective Global Pharmaceutical Patent Strategy: Key Elements and Considerations**

Chaired by Robert Pollock and Marian Flattery, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

This seminar will explain the practical impact of recent developments in U.S. and European law on patenting strategies for the pharmaceutical industry. The focus will be on how to ensure that new active ingredient patent applications are as robust as possible and that adequate protection is available for subsequent formulations, combination products, new uses and new forms (polymorphs, salts, enantiomers) to support product lifecycle management.

Please note: assa reserves the right to change the faculty and agenda to accommodate situations beyond its control.

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